K130423
Pg. 1 of 4

Revision 04-02-2013

APR 0 3 2013

510(k) Summary

Submitter:			Date of Preparation: April 02, 2013
Company / Institution name: **RICHARD WOLF MEDICAL INSTRUMENTS CORP.**			FDA establishment registration number: 14 184 79
Division name (if applicable): N.A.			Phone number (include area code): (847) 913 1113
Street address: 353 Corporate Woods Parkway			FAX number (include area code): (847) 913 0924
City: Vernon Hills	State/Province: Illinois	Country: USA	ZIP / Postal Code: 60061
Contact name: Mr. Ron Haselhorst			
Contact title: Quality Assurance / Regulatory Affairs Manager			
Parent Company:			
Company / Institution name: **Richard Wolf GmbH**			FDA establishment registration number: 96 111 02
Street address: Pforzheimer Str. 32			
City: Knittlingen	State/Province: Baden-Württemberg	Country: Germany	ZIP / Postal Code: 75438
Product Information:			
Trade name: The Richard Wolf ENDOCAM® Logic HD Camera System 5525		Model numbers: 5525xxx, 85525xxx, 8526xxxx	
Common name: Endoscopic Video Camera System		Classification name: 876.1500; FET - Endoscopic Video Imaging System / Component (Class II)	

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K080977	1 3 CCD ENDOCAM 5550 (Product Code: GCJ)	1 Richard Wolf Medical Inst. Corp.
2 K023659	2 1 CCD ENDOCAM 5520 (Product Code: KOG)	2 Richard Wolf Medical Inst. Corp.
3 K964173	3 C-mount objective lens, steam sterilizable	3 Richard Wolf Medical Inst. Corp

Device Description:
The Richard Wolf ENDOCAM® Logic HD Camera System 5525 is an endoscopic camera system for rigid and flexible endoscopes (e.g. Arthroscopes, Bronchoscopes, Cystoscopes, Hysteroscopes, Laparoscopes, Ureteroscopes, etc.). The Richard Wolf ENDOCAM® Logic HD Camera System 5525 allows the doctor to visualize the image of natural and artificial cavities through the endoscope by projecting images to a monitor for visual display and data storage during endoscopic diagnostic and therapeutic surgical procedures.

The Richard Wolf ENDOCAM® Logic HD Camera System 5525 consists of:

- ENDOCAM® Logic HD Controller(s)
- ENDOCAM® Logic HD Camera Head(s), and
- Objective Lens (Coupler).

Devices are used in conjunction with other ancillary equipment such as endoscopes, light source, monitors, printers, recorders, required cabling, etc.

The Richard Wolf ENDOCAM® Logic HD Camera Head(s) use 1CCD or 3CCD imaging systems to provide high definition (HD) visualization and quality images. The Richard Wolf ENDOCAM® Logic HD Camera Head cable connects to the ENDOCAM® Logic HD Controller, the ENDOCAM® Logic HD Controller relays the image from the endoscope with/without the use of an objective lens (coupler) to a video monitor; projection can be either analog or digital at the user's preference.

The Richard Wolf ENDOCAM® Logic HD Controller(s) is equipped with pre-programmed presets which can be selected via touch-screen, remote control, and/or keyboard. Self-made adjustments can be stored and individually named by user. Patient data and endoscopic images can be printed or stored directly onto USB flash drive.

The Richard Wolf ENDOCAM® Logic HD Camera System 5525 is compatible and can be integrated with the Richard Wolf RiwoNet / Core operating room system.

Devices included in the Richard Wolf ENDOCAM® Logic HD Camera System 5525 are reusable and do not require sterilization before use because there is no direct / in-direct patient contact. Methods of cleaning, disinfection, and sterilization are detailed in the Instruction for Use Manual; these instructions were developed by Richard Wolf using standards outlined in ANSI / AAMI ST:2004/(R) 2010 and FDA's Guidance "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance, Office of Device Evaluation April 1996.

This product is exclusively intended for use by specialized medical personnel and must only be used by medically qualified and adequately trained persons.

Intended Use:

The ENDOCAM® Logic HD Camera System 5525 has been designed for high-definition video endoscopy and can be used for both diagnostic and therapeutic interventions. The ENDOCAM® Logic HD Camera System 5525 is used in conjunction with other video equipment and endoscopic accessories.

Technological Characteristics:

The Richard Wolf ENDOCAM® Logic HD Camera System 5525 similarities to the predicate devices are:

- Has the same intended use and Indications and field of application.
- Incorporates the same basic design.
- Same operating principle.
- Are used in conjunction with other video equipment and endoscopic accessories.
- Can be integrated into the Richard Wolf operating room system.
- Reusable.
- Pre-programmed presets.
- Conforms to Safety Standards IEC 60601-1 and IEC 60601-1-2.

The Richard Wolf ENDOCAM® Logic HD Camera System 5525 differences to the predicate devices are:

- Controller:
  - Updated to allow for both digital and analog outputs.
  - Updated to allow for both 1CCD and 3CCD cameras.
  - Is equipped with additional Input / Output Sockets and interfaces (e.g. HDMI, Service Interface, PIP module, etc.).
  - Allows images to be stored and compressed.
- Camera:
  - Head can be angled or rotated.
  - Cable is available in 3.0mm, 5.0mm, and 8.0mm lengths.
  - Multipolar blade instead of Lemo.
- Objective Lens:
  - Snap on locking mechanism instead of locking collar.

Performance Data:

Design verification testing demonstrates that the devices function as intended, and the performance did not raise any new issues of safety and effectiveness.

Voluntary Safety and Performance Standards: The Richard Wolf ENDOCAM® Logic HD Camera System 5525 conforms to the following Safety Standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995. (General)
- IEC 60601-1-2 Edition 3:2007-03, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and Test.

Testing was completed by Independent laboratories, certifications are on file.

Clinical Data:

No clinical tests performed.

Rational for Substantial Equivalence:
The Richard Wolf ENDOCAM® Logic HD Camera System 5525 shares the same general indications for use, has similar function features and technological characteristics as the predicate devices, the minor difference(s) do not raise new questions for safety or effectiveness.

The Richard Wolf ENDOCAM® Logic HD Camera System 5525 was non-clinically tested to determine the safety and efficacy under the indications for use and meet aforementioned safety standards, same as the predicate devices.

For these reasons, The Richard Wolf ENDOCAM® Logic HD Camera System 5525 is substantially equivalent to the existing 510(k) cleared devices sold by: Richard Wolf Medical Instruments Corporation (K080977, K023659, and K964173).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 3, 2013

Richard Wolf Medical Instruments Corporation
% Mr. Ron Haselhorst
Quality Assurance and Regulatory Affairs Manager
353 Corporate Woods Parkway
VERNON HILLS IL 60061

Re: K130423
Trade/Device Name: The ENDOCAM® Logic HD Camera System 5525
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FET
Dated: February 15, 2013
Received: February 25, 2013

Dear Mr. Haselhorst:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K130423

Device Name: The ENDOCAM® Logic HD Camera System 5525

Intended Use:

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Prescription use ✓ (Part 21 CFR 801 Subpart D) and / or Over-The Counter Use ____ (Part 21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ANOTHER PAGE IF NEEDED

Concurrence of CDHR office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K130423